

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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JUN 1 2 1991

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fishers Lane, Room 11-44 Rockville, MD 20857 Hay

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,337,201 issued June 29, 1982, was filed on June 3, 1991, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC § 156.

Charles E. Van Horn

Manuel

Patent Policy & Programs Administrator

Office of the Assistant Commissioner for Patents

cc: Donald J. Barrack

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